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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT

PAPER NUMBER

1734

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,845	<b>Applicant(s)</b> PACETTI, STEPHEN D.	
	<b>Examiner</b> Laura Edwards	<b>Art Unit</b> 1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

*Specification*

The disclosure is objected to because of the following informality: on page 1, the cited patent application needs to be updated to include --U.S. Patent No. 6,743,462--.

Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed fails to teach or suggest how the pressure controller adjusts the pressure of the coating chamber above or below 760 torr based on the type of solvent utilized as suggested in claims 1 or based on the desire to increase or decrease the solvent evaporation rate as suggested in claim 9. In addition, the specification as originally filed fails to teach or suggest how the pressure controller adjusts the pressure of the coating chamber based on the vapor pressure of the coating solvent as suggested in claim 17. All the originally filed specification suggests is that the pressure controller is a pump (26, see page 4, first line of paragraph [0013]) and that the pressure employed in the pressure chamber depends on the type of solvent employed (see page 5, paragraph [0016], lines 9-10) as well as different pressure

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ranges being used for different solvents (see page 6). In other words, it is unclear how the apparatus having merely a pump to control pressure within the coating chamber regulates the pressure based on the solvent or solvent evaporation rate desired or the vapor pressure automatically. The specification as originally filed appears to be written for manual or user manipulation of the pressure controller in accordance with the solvent used and not an automated apparatus that regulates the pressure in the coating chamber based on the solvent.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear how the pressure controller adjusts the pressure within the chamber above or below 760 torr based on the type of solvent. What means or structure sets forth the type of solvent used so that the pressure controller can regulate the pressure in the chamber?

In claim 1, lines 4-5, "the coating process" lacks antecedent basis.

In claim 7, Applicant recites a limitation to the coating process and the composition used. However, it is unclear how this claim further structurally limits the apparatus of claim 1. It is unclear how an application can take place when the apparatus of claim 1 does not require or positively recite the coating composition. Claim one requires only a chamber and a pressure controller.

In claim 9, it is unclear how the pressure controller adjusts the pressure within the chamber above or below 760 torr based on a coating solvent evaporation rate. What means or

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structure sets forth the solvent evaporation rate so that the pressure controller can regulate the pressure in the chamber?

With respect to claim 15, see the response to claim 7.

In claim 17, it is unclear how the pressure controller adjusts the pressure within the chamber based on a vapor pressure of the coating solvent. What means or structure sets forth the vapor pressure of the coating solvent so that the pressure controller can regulate the pressure in the chamber?

With respect to claim 23, see the response above to claim 7.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 7-9, 11, 15-17, 19, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283).

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Shim et al teach an apparatus for coating implantable devices comprising a chamber (12) in which a coating composition supplied via a solvent (i.e., inert gas or combinations thereof) can be deposited on an implantable device and a pressure controller (34) for maintaining the chamber at a desired pressure (see col. 5, lines 7-8). Shim et al are silent concerning the pressure being adjusted based on the coating solvent being volatile or non-volatile. However, Shim et al recognize that the pressure within the chamber controls characteristics of the coating film as evidenced by col. 5, lines 2-4 such that it would have been within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition supplied so as to control coating film characteristics on the implantable device.

With respect to claim 2, see col. 5, lines 60-62 whereby a silane composition can be sprayed on the implantable device.

With respect to claim 3, Shim et al recognize the implantable device (24) being placed on an electrode or support.

With respect to claim 7, see col. 6, lines 44+.

With respect to claim 8, see col. 4, lines 60-64.

With respect to claims 9 and 17, the apparatus of Shim et al provides a pressure controller or regulating valve capable of adjusting pressure within the coating chamber in accordance with coating film characteristics.

Claims 4, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) as applied to claims 1-3, 7-9, 11, 15-17, 19, 23, and 24 above, and further in view of Vallana et al (US 5,370,684).

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The teachings of Shim et al have been mentioned above but Shim et al are silent concerning the chamber including a means for rotating the implantable device during coating. However, it was known in the art, at the time the invention was made, to provide in a plasma coating chamber, a rotatable support for rotating an implantable device during coating as evidenced by Vallana et al (see col. 7, lines 39-43). It would have been obvious to one of ordinary skill in the art to provide a rotational support as taught by Vallana et al in the plasma coating chamber of Shim et al in order to provide even coverage of coating about the entire surface of the implantable device.

#### *Allowable Subject Matter*

Claims 5, 6, 10, 13, 14, 18, 21, and 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura Edwards  
Primary Examiner  
Art Unit 1734

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September 23, 2004